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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,908	11/03/1998	OREST W. BLASCHUK	100086.409.	1195

500 7590 07/26/2002

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/26/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/185,908

Applicant(s)

BLASCHUK ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 2-20, 27-43, 46-49, 52-55 and 58-61 is/are pending in the application.
- 4a) Of the above claim(s) 8-20, 33, 34, 38-43, 46-49, 52-55 and 58-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2-6, 27-32, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/3/98 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment filed 5-11-02 (Paper No. 26), is acknowledged and has been entered.

Applicant's submission of the PCT application in English of WO 95/06211 (AG reference in the IDS filed 3-29-99) is acknowledged and the signed accompanying 1449 form is attached.

The outstanding new matter and written description rejections have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

MAINTAINED Claims 2 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by Bult et al. (Science 273:1058-1073, 1996)

Bult et al teach a 47mer protein that comprises the sequence IYSYV (see entire article) comprising at least 5 consecutive amino acids of SEQ ID NO:1, specifically residues Aaa-Baa-Ser/Ala-Tyr/Phe-Caa, based on nucleotide sequence of the prokaryotic organism *Methanococcus jannaschii*. It is noted that the claims as amended contain the limitation "wherein Aaa, Baa and Caa indicate amino acid residues that are present in a naturally occurring claudin". It is noted that Table I of the instant specification shows that naturally occurring mouse claudin-1 has the amino acid I for position Aaa and the amino acid Y for position Baa, and that naturally occurring claudin-2 has V at position Caa. Therefore, the referenced teachings anticipate the claimed invention.

Applicant traverses the rejection on the grounds that that the Bult et al reference fails to identify any description of a 47mer protein that comprises the sequence IYSYX. Accordingly, applicant is directed to the attached copy of NCBI sequence viewer which shows the 47mer protein described by Bult et al which has accession number D64402 and which is identified as hypothetical protein MJ0820, and an article by Koonin et al (Science 275:1489-1490 (1997) who teach on the last sentence of the legend for Figure 1 on page 1490 that MJ0820 is an open reading frame from an ATPase family. Said open reading frame is assumed to be translated, absent evidence to the contrary. Since the Office is not equipped to manufacture the claimed

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protein and/or the protein coded by the referenced nucleotides, nor to conduct comparisons, the burden is on the applicant to establish a patentable distinction between the claimed and referenced proteins. See In re Best, 195 USPQ 430, 433 (CCPA 1977).

Therefore, though applicant's arguments have been carefully considered, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MAINTAINED Claims 2-6, 27-32 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding the aspect of the rejection which concerns the specification's lack of disclosing the sequence identity of cell adhesion recognition containing peptides that actually reduced cell adhesion, Applicant traverses the rejection on the grounds that applicant is not required to specifically exemplify all embodiments of an invention. The examiner agrees, but notes the lack of any specific working embodiment. The examiner notes the declaration filed 5-11-02, which presents data showing that a peptide comprising SEQ ID NO:1 is capable of inhibiting the formation of tight junctions in epithelial cells. The examiner notes that said declaration has been considered for its one working embodiment of SEQ ID NO:1 wherein all the 8 residues of the generic SEQ ID NO:1 are specified. However, it is noted that an embodiment of one species does not necessarily make up a genus, and further the peptide used consisted of 10 amino acids. Applicants further assert that there is no sufficient evidentiary support in the action for doubting that the claimed modulating agent that comprises at least 5, 7 or 8 amino acids of a claudin CAR sequence having the formula of SEQ ID NO:1 is capable of modulating cell adhesion, and further notes two examples of tripeptides involved in modulating cell adhesion. However, the examiner notes that the lack of enablement of instant specification for modulating agent that comprises at least 5, 7 or 8 amino acids of a claudin CAR sequence having the formula of SEQ ID NO:1, is not due to the concept that short peptides can not modulate cell adhesion, but because the specification does not disclose which subsequences of 5, 7 or 8 amino acids in length of SEQ ID NO:1 can modulate cell adhesion. Applicant further asserts that the patent office has an initial burden to establish a prima facie case of non-enablement by providing sufficient supports for doubting the objective truth of the Statements in an application. Accordingly the examiner has attached a sheet containing a list of 17 proteins

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comprising at least five consecutive amino acids of SEQ ID NO:1 (namely IYSYX), none of which are attributed to be involved in cell adhesion, except claudin1. Therefore, it would require undue experimentation for one of skill in the art to predict which subsequences of SEQ ID NO:1 (cyclic or non-cyclic) would function as a cell adhesion molecule without further guidance from the instant specification.

Though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained essentially for the reasons of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

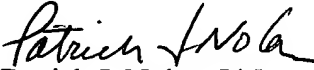
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD,
Patent Examiner, Group 1640
July 18, 2002


Patrick J. Nolan, PhD,
Primary Patent Examiner, Group 1640,